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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0322]

Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic Arsenic in Apple Juice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Arsenic in Apple Juice: Action Level" and two supporting documents entitled "Supporting Document for Action Level for Arsenic in Apple Juice" (the draft supporting document) and "A Quantitative Assessment of Inorganic Arsenic in Apple Juice" (the risk assessment document). The supporting documents are referenced in the draft guidance. The draft guidance identifies for the industry an action level for inorganic arsenic in apple juice that FDA considers protective of human health and achievable with the use of good manufacturing practices. It also describes FDA's intended sampling and enforcement approach.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1639.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three documents, a draft guidance for industry entitled “Arsenic in Apple Juice: Action Level” and supporting documents referenced in the draft guidance, including a draft supporting document entitled “Supporting Document for Action Level for Arsenic in Apple Juice” and a risk assessment document entitled “A Quantitative Assessment of Inorganic Arsenic in Apple Juice.” The draft guidance identifies an action level for inorganic arsenic in apple juice of 10 micrograms/kilogram (µg/kg) or 10 parts per billion (ppb), and identifies FDA’s intended sampling and enforcement approach. The draft supporting document reviews data on arsenic levels, health effects, and achievability, and explains FDA’s rationale for identifying an action level for inorganic arsenic in apple juice of 10 µg/kg. The risk

assessment document provides estimates of arsenic exposure and risk to humans at different hypothetical limits for inorganic arsenic in apple juice.

FDA considers the 10 µg/kg action level to be protective of human health and to be achievable with the use of good manufacturing practices, but FDA especially welcomes comments and information bearing on the achievability of 10 µg/kg, as compared with other potential action levels. Consistent with 21 CFR 109.6, FDA intends to consider the action level of 10 ug/kg or 10 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on arsenic in apple juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic or written comments regarding this document according to the instructions in the "ADDRESSES" section of this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance, the draft supporting document, and the risk assessment document at either

http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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